IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8965

Bartle, J. November 15, 2012

Judy E. Clark ("Ms. Clark" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Rodger A. Clark, Ms. Clark's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Gregory R. Boxberger, M.D., F.A.C.C. Dr. Boxberger is no stranger to this litigation. According to the Trust he has signed in excess of 74 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated November 20, 2001, Dr. Boxberger attested in Part II of Ms. Clark's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

fraction in the range of 50% to 60%.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $476,887.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, Laddeus L. Sutton, M.D., F.A.C.C., stated that claimant had "[m]ild mitral regurgitation by color Doppler flow imaging." Dr. Sutton, however, did not specify a percentage as to claimant's level of mitral regurgitation.[6] Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In November, 2003, the Trust forwarded the claim for review by Eduardo A. Arazoza, M.D., F.A.C.C., one of its auditing

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4. Dr. Boxberger also attested that claimant suffered from mild aortic regurgitation. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

6. Claimant also submitted an echocardiogram report prepared in May, 2002 by Dr. Boxberger based on her November 20, 2001 echocardiogram. In this report, Dr. Boxberger stated that claimant had "moderate mitral regurgitation based on RJA to LAA ratio of .20."

cardiologists. In audit, Dr. Arazoza concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild regurgitation. In support of this conclusion, Dr. Arazoza explained that "[t]he [mitral regurgitation] is mild. Off line planimetry must have been performed as there is no evidence of planimetry on the tape."

Based on Dr. Arazoza's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Clark's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In contest, claimant submitted affidavits from Dr. Boxberger, Roger W. Evans, M.D., F.A.C.P.,[8] F.A.C.C., and Dan A. Francisco, M.D., F.A.C.C. In his affidavit, Dr. Boxberger confirmed his previous finding that claimant had moderate mitral regurgitation with an RJA/LAA of approximately 20%. Dr. Evans stated that "claimant's echocardiogram of 11/20/01 reveals 'moderate' mitral valve regurgitation with an RJA/LAA ratio of approximately 20%." Dr. Francisco also

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Clark's claim.

8. Dr. Evans also is no stranger to this litigation. According to the trust he has signed in excess of 318 Green Forms on behalf of claimants seeking Matrix Benefits.

concluded that claimant's echocardiogram tape showed moderate mitral regurgitation and found "an RJA/LAA ratio of 20%." Claimant argued, therefore, that she had established a reasonable medical basis for her claim because three Board-Certified cardiologists independently agreed that she had moderate mitral regurgitation. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his personal opinion ... and the 'reasonable medical basis' standard." (Emphasis in original.)

The Trust then issued a final post-audit determination, again denying Ms. Clark's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Clark's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5245 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on October 18, 2005, and claimant submitted a sur-reply on November 14, 2005. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Clark repeats the arguments she made in contest; namely, that the opinions of Dr. Boxberger, Dr. Evans, and Dr. Francisco provide a reasonable medical basis for the finding of moderate mitral regurgitation. Claimant also contends that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and the auditing cardiologist, Dr. Arazoza. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Clark contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable.

In response, the Trust agues that the opinions of Dr. Evans and Dr. Francisco do not establish a reasonable medical basis for the claim because they "merely parrot the representations of Dr. Boxberger." The Trust also notes that none of claimant's physicians address the original echocardiogram report prepared by Dr. Sutton, which indicates that claimant had only mild mitral regurgitation. Finally, the Trust contends that inter-reader variability does not establish a reasonable medical basis for Ms. Clark's claim because "the Auditing Cardiologist's finding that [claimant] has only mild mitral regurgitation cannot be ascribed to inter-reader variability."

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical

basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Burke found that:

> My impression of the November 20, 2001 echocardiogram, by visual inspection, is that the mitral regurgitation is trace to mild. There are no color flow Doppler images in the apical two chamber view and the color flow Doppler imaging in the subcostal view is suboptimal to assess for severity of mitral regurgitation.
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> Using representative beats from the apical four chamber view, I measured several frames with the RJA/LAA ratio to be no greater than 14.3%. Using representative beats from the apical long axis view, I measured the RJA/LAA ratio to be no greater than 10.8%. My overall evaluation is that the mitral regurgitation is trace to mild in the apical four chamber view and mild in the apical long axis view.
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> I was unable to planimeter a regurgitant jet area in the parasternal long axis view because of the absence of a regurgitant jet of even a small area. This view showed a few examples of a low velocity (dark-blue) image. These were evanescent in real-time and did not correlate either in location or timing with a mitral regurgitant jet. I believe these represent artifact and/or backflow.

After reviewing the entire show cause record, we find claimant's arguments are without merit. Claimant does not adequately refute the findings of the auditing cardiologist or the Technical Advisor. She does not rebut the auditing cardiologist's determination that "[t]he [mitral regurgitation] is mild" and that "[o]ffline planimetry must have been

performed."[10] Nor does she challenge Dr. Burke's conclusion that "the mitral regurgitation is trace to mild in the apical four chamber view and mild in the apical long axis view."[11] Although claimant submitted the reports of several cardiologists, neither claimant nor her experts identified any particular error in the findings of the auditing cardiologist or the Technical Advisor. They also do not dispute the reviewing cardiologist's determination that claimant's echocardiogram demonstrated only mild mitral regurgitation. Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Claimant's reliance on inter-reader variability to establish a reasonable medical basis for Dr. Boxberger's representation that Ms. Clark had moderate mitral regurgitation also is misplaced. The concept of inter-reader variability already is encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be reasonable where the Technical Advisor concluded that the RJA/LAA ratio was no greater than 14.3% in the apical four chamber view and 10.8% in the apical long-axis view. Adopting claimant's argument that

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10. For this reason as well, we reject claimant's argument that the auditing cardiologist substituted his personal opinion for the diagnosis of the attesting physician.

11. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

inter-reader variability expands the range of moderate mitral regurgitation by ±15% would allow a claimant to recover benefits with an RJA/LAA as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.[12]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Clark's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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12. Moreover, the Technical Advisor specifically stated that "[e]ven accounting for inter-reader variability in the assessment of mitral regurgitation, an echocardiographer could not reasonably conclude that the echocardiogram dated November 20, 2001 indicates this Claimant has more than mild mitral regurgitation."